Notice of Allowability	Application No. 10/675,729	Applicant(s) PESHOFF, MICKEY L.	
	Examiner JOHN PAK	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to _____.

2. ☒ The allowed claim(s) is/are *1-16 and 29-44 [renumbered as 1-32]*.

3. ☐ The drawings filed on _____ are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 9/30/03
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

JOHN PAK
PRIMARY EXAMINER
GROUP 1600

Claims 1-28 are pending in this application.

Restriction Requirement

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-16, drawn to compositions comprising zinc oxide, fat soluble vitamins, antibacterial agent, antifungal agent and an effective amount of calcium channel blocker, classified in various subclasses in classes 424 and 514, depending on the chemical structure of the components.

II. Claims 17-28, drawn to method of healing wounds by contacting a wound to be healed with a therapeutic composition comprising an effective amount of at least two fat soluble vitamins admixed with zinc oxide and a calcium channel blocker, classified in various subclasses in classes 424 and 514, depending on the chemical structure of the components.

The inventions are distinct, each from the other because:

Inventions of Group I and Group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product, such as for example in providing nutritional supplements.

Further, the search and examination of the entire application would place an undue burden on the examiner if the restriction were not required. The components utilized in this application are very broad and the proper search for this application is quite demanding due to the breadth of the active components. Therefore, to additionally search and examine a divergent and distinct concept such as a specific method of utilizing the composition from amongst myriad conceivable uses possible therefor would place a serious burden on the Examiner.

Consequently, for the reasons of distinctness and undue burden the restriction requirement is deemed to be proper.

Telephonic Restriction Requirement and Applicant's Election

During a telephone conversation with Mr. Keaty on 3/17/05 (and confirmed on 3/31/05) an election was made without traverse to prosecute the invention of Group I, claims 1-16. Affirmation of this election must be made by applicant in replying to this Office action.

Fee Authorization

Additional fee (for claims in excess of 20) is required in order to make an examiner's amendment which places this application in condition for allowance. During telephone conversations conducted on 3/31/05 and 4/28/05, Mr. Keaty authorized the Director to charge **Deposit Account No. 11-0260** the required fee of **$100** for the

additional claims (four more than previously paid for) and authorized the following examiner's amendment[1]. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Examiner's Amendment

Amendments to the Claims

Cancel the non-elected claims 17-28.

Rewrite claim 2 as shown below.

Claim 2. (Currently amended) The composition of claim 1, wherein said calcium channel blocker is 3,5-pyridinedicarboxylic acid, 1,4-dihydro-2,6-dimethyl-4-(2-nitrophenyl)-dimethyl ester, which has the chemical formula of $C_{17}H_{18}N_2O_6$.

Amend claims 7 and 16 as follows[2].

Claim 7, line 3: delete "nimorazoel" and insert --- nimorazole --- .

Claim 7, line 4: delete "hentamycin," .

Claim 7, last line: delete "clindamycin, chloramphicol" and insert --- chloramphenicol --- .

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[1] Applicant already paid for 28 claims. Upon the entry of the Examiner's Amendment, there will be 32 claims pending and allowed. Hence, a fee for four additional claims must be paid. As a small entity, the fee is 4 X $25 = $100.

[2] Claim 7 contains a misspelling for nimorazole and recites clindamycin twice. Claim 7 also contains a misspelling for chloramphenicol (note the correct spelling in claim 6, last line).

Claim 16, line 2: delete "comprises" and insert --- contains --- .

Rewrite claim 9 as shown below.

Claim 9. (Currently amended) The composition of claim 1, wherein said antifungal agent is selected from the group consisting of astemizole, clotrimazole, omeprazole, econazole, oxiconazole, sulconazole, fluconazole, ketoconazole, itraconazole, terbinafine, and mixtures thereof.

Add the following new claims.

Claim 29. (New) A method of healing wounds in mammals by repairing body tissue in mammals, comprising the steps of:

contacting a wound to be healed with a therapeutic composition comprising an effective amount of the composition of claim 1.

Claim 30. (New) A method of healing wounds in mammals by repairing body tissue in mammals, comprising the steps of:

contacting a wound to be healed with a therapeutic composition comprising an effective amount of the composition of claim 2.

Claim 31. (New) A method of healing wounds in mammals by repairing body tissue in mammals, comprising the steps of:

contacting a wound to be healed with a therapeutic composition comprising an effective amount of the composition of claim 3.

Claim 32. (New) A method of healing wounds in mammals by repairing body tissue in mammals, comprising the steps of:

contacting a wound to be healed with a therapeutic composition comprising an effective amount of the composition of claim 4.

Claim 33. (New) A method of healing wounds in mammals by repairing body tissue in mammals, comprising the steps of:

contacting a wound to be healed with a therapeutic composition comprising an effective amount of the composition of claim 5.

Claim 34. (New) A method of healing wounds in mammals by repairing body tissue in mammals, comprising the steps of:

contacting a wound to be healed with a therapeutic composition comprising an effective amount of the composition of claim 6.

Claim 35. (New) A method of healing wounds in mammals by repairing body tissue in mammals, comprising the steps of:

contacting a wound to be healed with a therapeutic composition comprising an effective amount of the composition of claim 7.

Claim 36. (New) A method of healing wounds in mammals by repairing body tissue in mammals, comprising the steps of:

contacting a wound to be healed with a therapeutic composition comprising an effective amount of the composition of claim 8.

Claim 37. (New) A method of healing wounds in mammals by repairing body tissue in mammals, comprising the steps of:

contacting a wound to be healed with a therapeutic composition comprising an effective amount of the composition of claim 9.

Claim 38. (New) A method of healing wounds in mammals by repairing body tissue in mammals, comprising the steps of:

contacting a wound to be healed with a therapeutic composition comprising an effective amount of the composition of claim 10.

Claim 39. (New) A method of healing wounds in mammals by repairing body tissue in mammals, comprising the steps of:

contacting a wound to be healed with a therapeutic composition comprising an effective amount of the composition of claim 11.

Claim 40. (New) A method of healing wounds in mammals by repairing body tissue in mammals, comprising the steps of:

contacting a wound to be healed with a therapeutic composition comprising an effective amount of the composition of claim 12.

Claim 41. (New) A method of healing wounds in mammals by repairing body tissue in mammals, comprising the steps of:

contacting a wound to be healed with a therapeutic composition comprising an effective amount of the composition of claim 13.

Claim 42. (New) A method of healing wounds in mammals by repairing body tissue in mammals, comprising the steps of:

contacting a wound to be healed with a therapeutic composition comprising an effective amount of the composition of claim 14.

Claim 43. (New) A method of healing wounds in mammals by repairing body tissue in mammals, comprising the steps of:

contacting a wound to be healed with a therapeutic composition comprising an effective amount of the composition of claim 15.

Claim 44. (New) A method of healing wounds in mammals by repairing body tissue in mammals, comprising the steps of:

contacting a wound to be healed with a therapeutic composition comprising an effective amount of the composition of claim 16.

Amendments to the Specification

Specification page 1, three lines below the Title: delete "which is a" and insert --- which is now U.S. Patent No. 6,660,306, which is a --- .

Specification page 4, line 21: delete line 21 and insert therefor --- acid, 1,4-dihydro-2,6-dimethyl-4-(2-nitrophenyl)-dimethyl ester, which has the chemical formula of $C_{17}H_{18}N_2O_6$. ---- .

Specification page 5, line 9: delete "nimorazoel" and insert --- nimorazole --- .

Specification page 5, line 11: delete "polymixin" and insert --- polymyxin --- .

Specification page 5, line 13: delete "chloramphicol" and insert --- chloramphenicol --- .

Specification page 5, line 16: delete "econozole, oxiconozole, sculconazole" and insert --- econazole, oxiconazole, sulconazole --- .

Specification page 5, line 17: delete "terbinafien" and insert --- terbinafine --- .

Specification page 69, line 2: delete "econozole, oxiconozole," and insert --- econazole, oxiconazole, --- .

Specification page 69, line 3: delete "sculconazole" and insert --- sulconazole --- .

Comments Regarding Rejoinder

It is noted that the examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims

and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

In accordance with the current rejoinder practice, the above Examiner's Amendment has added method claims that include all the limitations of the patentable composition claims. Consequently, the restriction requirement between the product claims (i.e. composition claims) and the rejoined process claims are withdrawn.

Further, it is noted that method claims that do not include all the limitations of the patentable composition claims have *not* been rejoined and restriction between the product and such method claims are maintained.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance: the common denominator with respect to all of the claims is a mixture of zinc oxide, at least two fat soluble vitamins, an antifungal agent, an antibacterial agent and a calcium channel blocker. The mixture and the claimed method of use thereof is unquestionably novel. Further, adequate motivation or suggestion to incorporate the six minimum composition components cannot be found in the prior art. This is particularly the case in view of prior art such as Medline abstract 2000206072, which discloses that the calcium channel blocker diltiazem did not affect wound healing. Given applicant's asserted benefit of

tissue and wound healing (e.g., specification page 6), the claimed invention *as a whole* must be found allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Gary Kunz, can be reached on **(571)272-0887**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN PAK
PRIMARY EXAMINER
GROUP 1600